



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

91497d

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**WARNING LETTER**

**NWE-31-01W**

VIA FEDERAL EXPRESS

July 2, 2001

Hitoshi Okana  
General Manager  
True World Foods, Inc., d.b.a. Rocky Neck Seafoods  
22 Food Mart  
Boston, MA 02118

Dear Mr. Okana:

We inspected your firm, located at 22 Food Mart, Boston, MA, on June 13 and 14, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during previous inspections, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- You must implement the monitoring procedure listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record temperatures at the receiving critical control point, (CCP) to control the histamine hazard listed in your HACCP plan for scombrotoxic species of fish received at your firm.

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for vacuum-packed yellow tail does not list the food safety hazard of *C. botulinum*.
- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for scombotoxigenic species does not list a critical limit at the storage CCP to control the histamine hazard, for example the presence of ice.

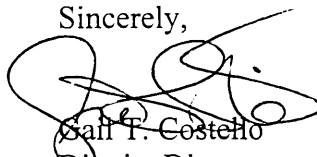
We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your modified HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 1708.

Sincerely,



Paul F. Costello  
District Director  
New England District Office

Cc:

Tamotsu Nakamura  
President  
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